

We claim:

1. Mammals' milk comprising a recombinant protein, said protein being produced along with or in said milk by the mammals.

5           2. The milk according to claim 1, wherein the mammal is selected from the group consisting of cows, sheep, goats, pigs, mice, oxen and camels.

          3. The milk according to claim 1, wherein the recombinant protein is selected from the group consisting  
10 of coagulation factors VIII and IX, human or animal serum albumin, tissue plasminogen activator (TPA), urokinase, alpha-1 antitrypsin, growth hormone from animal or human sources, Mullerian Inhibiting Substance (MIS), cell surface proteins, insulin, interferons, interleukins, milk  
15 lipases, antiviral proteins, peptide hormones, immunoglobulins, lipocortin and fragments and derivatives thereof.

          4. A process for the production of a recombinant protein comprising the steps of collecting milk  
20 from a transgenic mammal characterized by an expression system comprising a milk-specific promoter or a promoter specifically activated in mammary tissue operatively linked to a DNA sequence coding for the recombinant protein through a DNA sequence coding for a signal  
25 peptide effective in secreting and maturing the recombinant protein in mammary tissue and isolating the recombinant protein from the milk.

          5. The process according to claim 4, wherein said expression system also includes a 3' untranslated  
30 region downstream of the DNA sequence coding for the recombinant protein.

6. The process according to claim 4, wherein said expression system also includes a 5' untranslated region between said promoter and the DNA sequence coding for the signal peptide.

5           7. A DNA sequence comprising a milk-specific promoter or a promoter specifically activated in mammary tissue operatively linked to a DNA sequence coding for a recombinant protein through a DNA sequence coding for a signal peptide effective in secreting and maturing  
10 the recombinant protein in mammary tissue.

8. The DNA sequence according to claim 7, wherein said DNA sequence also includes a 3' untranslated region downstream of the DNA sequence coding for the recombinant protein.

15           9. The DNA sequence according to claim 7, wherein said DNA sequence also includes a 5' untranslated region between said promoter and the DNA sequence coding for the signal peptide.

20           10. A transgenic mammal, excluding humans, comprising a DNA sequence according to any one of claims 7 to 9.